



PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application

Inventor: Apollon Papadimitriou

Group: 1653

Serial No. 09/853,731, filed May 11, 2001
(Case Docket No. 20619 US)

Examiner: Kam, Chih Min

For: **ERYTHROPOIETIN COMPOSITION**

SECOND DECLARATION OF APOLLON PAPADIMITRIOU, Ph.D.
UNDER 37 CFR § 1.132

Commissioner of Patents
Washington, D.C. 20231

Sir:

I, Apollon Papadimitriou, a citizen and resident of Germany, declare that:

1. I am the sole inventor named in the above-captioned patent application Serial No. 09/853,731, filed May 11, 2001, internally designated as "CD 20619 US," and am familiar with the contents of this application (hereinafter "the captioned application").

2. Since October 1996, I have been employed by Roche Diagnostics GmbH, Penzberg, Germany. My present title is Head of Protein Analytics.

3. I am also familiar with the pharmaceutical compositions disclosed in US Patent 6,583,272 B1, filed June 27, 2000, to Pascal Bailon, specifically formulations A-I presented in Table 3, Example 8. As stated in my earlier declaration dated February 5, 2004,

submitted in the captioned application, I again confirm that I am the source of the pharmaceutical compositions and the data related thereto that is disclosed in the Bailon '272 patent and am the sole inventor of these compositions.

4. Documentary confirmation that I am the inventor of the formulations disclosed and claimed in the captioned application as well as the source of the formulations disclosed in Example 8, Table 3, of the Bailon '272 patent, is attached herewith as Exhibits A - C.

5. Exhibit A is a copy of the front page and pages 6 to 13, 19 to 20, 44 to 46 and 48 of my laboratory notebook LT823/1, as well as the front page and pages 136 to 143 and 147 to 155 of my laboratory notebook LT1671/001. These notebook pages contain stability data of various formulations I developed comprising a pegylated erythropoietin conjugate, lot numbers "Ch. 1109," "Ch. 2109," and "Ch. 6020." As noted on these pages, I obtained the conjugate from "Nutley", specifically from Mr. Pascal Bailon, one of my colleagues working at Hoffmann-La Roche Inc., in Nutley, New Jersey. The date on these laboratory pages is November 24 1999; February 3, 2000; March 1, 2000; and March 7, 2000.

6. A patent application directed to the formulations described in my notebooks was filed in Europe as application 00110355.5 on May 15, 2000. As is reflected in the current record, the above-captioned US application claims the benefit of European application 00110355.5.

7. Shortly after European application 00110355.5 was filed, the patent attorney that prepared this application gave a copy of it to the US patent attorney that was working on the pending US Bailon application (internally designated as "case 20431"). Attached as Exhibit B is a copy of European application 00110355.5 as it was transmitted to the US attorney on May 16, 2000 as well as the e-mail forwarding this application. Subsequently, on June 16, 2000, I was copied on an e-mail chain verifying that a copy of my application (Case 20619) had been forwarded to the US attorney on May 16, 2000, and confirming

that the pegylated erythropoietin conjugate that was used in the formulations described in Examples 8, 9 and 10 of my European application (Case 20619) was the Bailon compound that was by then known as Ro 50-3821, which is a compound within the scope of the Bailon 6,583,272 patent (Case 20431). A copy of this e-mail chain is included as Exhibit C.

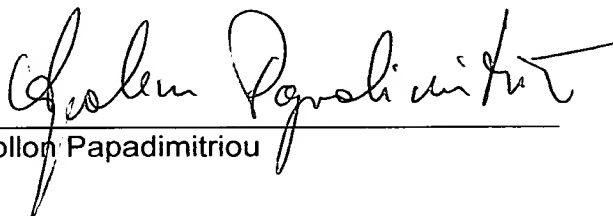
8. The pegylated erythropoietin conjugate that was used in my formulations disclosed and claimed in the above-captioned application originated from Pascal Bailon. A comparison of the product synthesis examples of the Bailon '272 patent will verify that these are essentially the same as in my patent application. Analogously, a comparison of the formulations described in the Bailon '272 patent in Example 8, Table 3, will show that these formulations are the same as those disclosed in Table 3, Example 10, of my original European priority application 00110355.5, confirming that this information originated with me.

9. At the time European application 00110355.5 was filed, I believed that the formulations described therein were the best way I knew of to prepare an injectable pharmaceutical composition comprising the Bailon conjugates.

I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: 6/01/2006

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Apollon Papadimitriou